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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,960	12/22/2000	Michael Strobel	02581-P0350A	8504

24126 7590 10/11/2006

ST. ONGE STEWARD JOHNSTON & REENS, LLC  
986 BEDFORD STREET  
STAMFORD, CT 06905-5619

EXAMINER

BRANDT, ADAM CURTIS

ART UNIT	PAPER NUMBER
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3771

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/745,960	STROBEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Adam Brandt	3743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-45 is/are allowed.
- 6) ☒ Claim(s) 25, 27-32 and 35 is/are rejected.
- 7) ☒ Claim(s) 26, 33 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 25, 27-32, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over**

**Huebner (U.S. Patent No. 5,456,685) in view of Ross et al. (U.S. Patent No. 5,470,334).**

Huebner discloses an interference screw (12) for anchoring a transplant (60) to a bone (56, 62). The screw (12) includes a recess (68) located therein. Huebner also discloses a tool ("driver"; col. 4, line 15) for inserting the screw into an opening in the bone. In Figs. 3-5, the screw body (12) contacts the transplant (60) positioned between the screw body and a side of the opening in the bone to anchor the transplant to the bone. Thus, Huebner discloses the claimed invention with the exception of at least one extending groove running substantially the length of the screw body, a biodegradable material and the specifics of the drive tool. However, Ross, which also relates to an interference screw including a recess (50), teaches that it is known to

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design a biodegradable screw including at least one axially extending groove (36). Furthermore, Ross discloses a driver (60) that corresponds to recess (50) in the screw head for centering the tool with respect to the screw body during insertion. Therefore, it would have been obvious to one skilled in the art to incorporate the drive tool of Ross into the interference screw of Huebner for the purpose of providing a drive tool which is capable of withstanding high driving forces as taught by (Ross, cols. 1-2).

As shown in Fig. 5 of Ross, the drive element (60) extends substantially the length of the at least one axially extending groove (36).

Fig. 5 of Ross also discloses that the depth of the at least one axially extending groove is such that the at least one drive element of the tool lies within the at least one axially extending groove and does not extend beyond the outer periphery of the screw body.

Figs. 2 and 5 of Ross further teach that the depth of the at least one axially extending groove is such that the at least one drive element of the tool is housed within the at least one axially extending groove without extending radially beyond a threading of the shaft.

The recess (68) of Huebner and the recess (50) of Ross, both, are configured as a channel completely passing through the screw body.

As shown in Fig. 2 of Ross, the at least one axially extending groove opens axially at the screw head.

Ross further discloses a bridge (Fig. 4) for bridging the at least one axially extending groove in a circumferential direction.

Huebner teaches that the transplant may be selected from the group consisting of: a tendon, a ligament and the combinations thereof.

***Response to Amendment***

The Request for Continued Examination (RCE), filed on 6/15/2006, and the amendment filed on 3/09/2006, has been entered. Examiner acknowledges that claims 26 and 36 have been amended. Subsequently, claims 25-45 are under consideration.

***Response to Arguments***

Applicant's arguments filed 3/09/2006 have been fully considered but they are not persuasive.

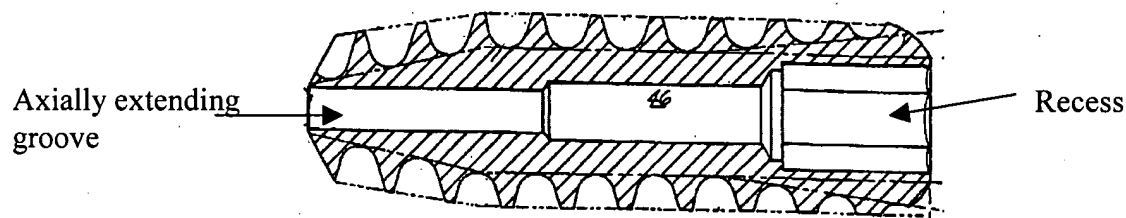
**In regards to claim 25, 27-32:** The Applicant is arguing that Huebner (USPN 5,456,685) in view of Ross (USPN 5,470,334) does not disclose the proposed invention, in particular, a “screw head having a recess located therein” and a “tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion.”

Proximal, as defined by the example given in page 10, paragraph 3 of the Applicant's argument, is the end furthest from the initial penetration of bone. In addition, the Applicant is stating it is well known that the head of a screw is located at the proximal end and that the head is typically where a driving tool would be received.

The Applicant states that Ross does not disclose a recess in the proximal end of the screw. The Applicants quotation of Ross clearly teaches that the screw of Ross does indeed have a recess in the proximal end of the screw, by definition of the Applicant, and that the recess is meant for the reception of a driving tool. While Ross discloses the proximal end (14) and Distal end (16), this appears to be unconventional use of the terminology. It is clear that the screw of Ross has a proximal end with a recess for receiving a driving tool.

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The Applicant further argues that Hueber does not anticipate claim 25 and all claims dependent from 25 because the head contains a hexagonal socket and there is a 3-stage channel through the screw body. The Applicant states that Hueber does disclose “at least one axially extending groove” that receives a drive element and a “screw head having a recess located therein” that receives a tool protrusion.

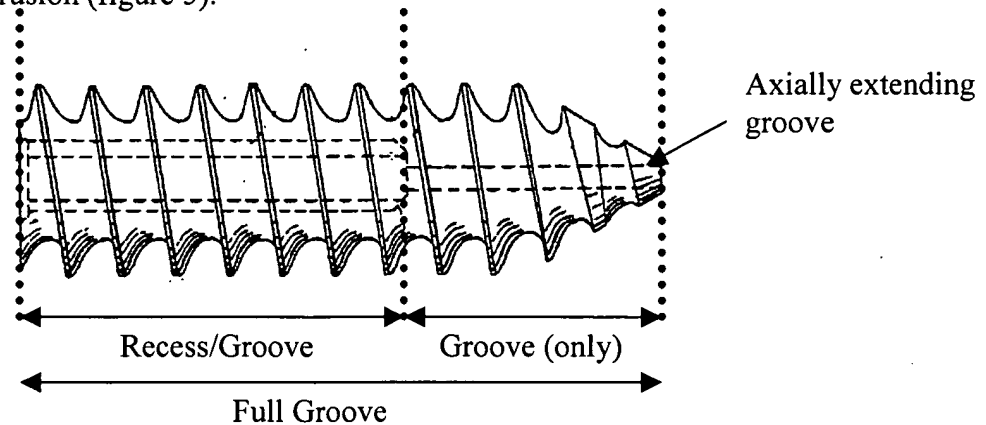


Huebner does in fact disclose a recess in head of the screw as seen in the figure above. Huebner recites that “screw 12 is fitted onto a driver (not shown) by inserting a hexagonal front end of the driver into socket 42.” (col 3, ln 34-36). Hueber recites that the intended use of the recess in the screw head is to receive a tool protrusion. By Applicant’s definition of proximal as stated above, the proximal end is the end furthest from the initial penetration of bone. The recess of Hueber (seen in the figure above) is most definitely located in the proximal end of the screw. Therefore, the recess in the proximal end of screw of Hueber is clearly meant to receive a driving tool.

The Applicant states the Ross does not anticipate claim 25 and all claims dependent from 25 because Ross fails to disclose “at least one axially extending groove” that receives a tool drive element and a “screw head having a recess located therein” that receives a “tool having a protrusion.” Ross fully discloses an axially extending groove that runs the complete length of the screw from the proximal end to the recess. In combination with the recess, the axial groove

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continues to the distal end of the screw (see figure below). Ross discloses that the groove/recess does receive a tool protrusion (figure 5).



The Applicant states that Ross fails to disclose a “tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion.” The Applicant recites from the patent to Ross that a guide wire is used to align the tool. The screw has a recess/groove through the center of the screw. The recess of the screw has a radial 3-pronged particular pattern (figure 2). The corresponding driving element is cut to fit this particular pattern (figures 3-6). The act of inserting the tool into the recess would center the tool with respect to the screw without the use of the guide wire. Therefore, the screw and tool of Ross does disclose a “tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion.”

The Applicant argues that a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no motivation or suggestion to make such a modification. The Examiner agrees with the Applicant statement. The Examiner does not believe that the proposed modification suggested by the Applicant in the continued

paragraph from page 13 to 14 is presented in the office action mailed 1/10/2006. The modification proposed by the Applicant relocates the guide bore from the distal end of the screw to the proximal end, as defined by the applicant. The Applicant argues that this modification would destroy the prior art such that it could not be used for intended use. Neither Hueber or Ross suggest this modification.

The Applicant's claim reads, "at least one axially extending groove substantially the length of the said screw body." The Examiner interprets "substantially" as being 51 percent or more of the entire screw body. As the Applicant quoted Ross on page 12, "length of drive recess 30 from proximal end 14 to end wall 32 is approximately 48% to 95% overall length of body 12 measured from proximal end 14 to distal end 16." (Ross, col 5 ln 15-18). **As seen from the figure above, the recess and groove jointly occupy the same location in the proximal upper half of the screw.** This being said, Ross, as quoted previously, recites that the recess can substantially extend through the body of the screw.

The Applicant argues the point of why would one skilled in the art wish to have a recess in the head of the screw and have a guide bore at the distal end of screw. The Applicant contends that the recess and guide bore accomplish the same task. In addition, the Applicant argues that adding a protrusion to the tool for centering the tool would accomplish the same challenge met by the guide wire. Ross discloses that the guide bore encompasses the guide wire which is formed in the body to extend longitudinally from the drive recess to the distal end for guiding the screw on a guide wire (col 3, ln 61-64). The tool with a protrusion centers the screw on the tool, but the guide bore houses the guide wire which is connected to the location where



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the screw is to be inserted (col 6, ln 65 to col 7, ln 20). Therefore, the guidebore and the tool with a protrusion accomplish different goals. One skilled in the wanting to accomplish both goals would employ such a design.

The applicant argues that Ross teaches that one skilled in the art would not implement a recess that degrades the thickness of the walls of the bone screw. Ross teaches that a hexagonal recess is not the best selection in combination with a bioabsorbable material because of the stresses concentrated on the sidewalls of the recess (col 2, ln 5-20). The extrinsic evidence provided by Rego, Jr. et al. (USPN 5,364,400) teaches that an interference bone screw can be made of a bioabsorbable material and contain a hexagonal recess (col 5, ln 9-13 and col 5 ln 59 to col 6 ln 6). Therefore, Ross teaches that a hexagonal recess is not recommended because of the structural qualities of a bioabsorbable materials, but Rego, Jr. et al. teaches that is possible to use a hexagonal recess in an application utilizing bioabsorbable materials.

Applicant's arguments, filed 3/09/2006, with respect to claims 36-43 have been fully considered and are persuasive. The rejection of claims 36-45 has been withdrawn. The Applicant's arguments in combination with the amendment made to claim 36 has established patentability over the prior art of Hueber and Ross for claim 36 and all dependent claims.

Applicant's arguments, filed 3/09/2006, with respect to claims 26 have been fully considered and are persuasive. The objection of claims 26 has been withdrawn. The amendment

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to claim 26 makes the claim distinguishable from claim 25. Therefore, the claim 26 is no longer a substantial duplicate of claim 25.

***Allowable Subject Matter***

Claims 36-45 are allowed. Claims 26, 33, 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB

Adam Brandt  
Examiner  
Art Unit 3743

  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700